

DETAILED ACTION

This office action is in response to the Amendment filed 18 March 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 is indefinite because it merely recites a use (i.e. enabling visual inspection and identification) without any active, positive steps delimiting how this use is actually practiced. (See MPEP 2173.05 (q)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Firestone et al. (U.S. Patent 5,799,837), in view of Forte et al. (U.S. Patent Application Publication 2001/0048988). Firestone et al., hereafter "Firestone," show that it is known to carry out a method for enabling visual inspection and identification of formulation (It is held that this function would normally be performed by Firestone's process/article, and therefore this element is considered to be suggested by Firestone's process/article (See MPEP 2112.02), the method comprising forming a bottle useful as a pharmaceutical container and dispenser (Column 1, lines 31-38; Column 5, lines 28-31) comprising providing a mixture of polypropylene resin comprising UV absorbers (i.e. blockers)

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(Column 2, lines 51-54; Column 9, lines 12-13), and forming the heated UV absorbent mixture into a cylindrical squeezable bottle having a thickness of between 0.5mm and about 2mm (Column 3, lines 17-21) with a volume of 10 cc (Column 2, lines 60-61; 10mL = 10cc); disposing an ophthalmic pharmaceutical formulation into said bottle (Column 4, lines 66-67; Column 5, lines 1-11; Column 10, lines 63-64; It is being interpreted that chlorine dioxide is a known ingredient in ophthalmic pharmaceutical formulations.); and sealing the bottle (Column 12, lines 1-3). It is noted that "using bottle properties to visually inspect the formulation in the bottle and identify the formulation by a color of the bottle" is merely intended use of the positively-claimed method steps and therefore is not a positively-claimed step of the claimed method (see MPEP 2111.01). Further, it is held that this function would normally be performed by Firestone's process/article, and therefore this element is considered to be suggested by Firestone's process/article (See MPEP 2112.02). Firestone does not show a specific mixing order to obtain his mixture. However, selection of any order of mixing ingredients is prima facie obvious (See MPEP 2144.04 (IV)(C)). Also, Firestone does not specifically show first, second, and third sets of resin pellets, or providing dyestuffs to the pellets. Forte et al., hereafter "Forte," show that it is known to carry out a method of making a bottle useful as a pharmaceutical container (Para 0008), including providing combinations of polypropylenes which contain dyes in amounts enabling transmission of visual blue wavelength and UV absorbers (i.e. blockers) (Para 0015-0017; blue tinting=dye in an amount enabling transmission of visual blue wavelength; It is known in the art that individual blends of molding material, in this case, polypropylenes, will originate in pellet form, including various desired additives such as the claimed dyestuffs and UV blockers. In order to form the final molding material, the different pellet mixtures will be mixed together to form a masterbatch.), heating said UV blocker final mixture (Para 0024), and forming the bottle (Para 0027). Forte and Firestone are combinable because they are concerned with a similar technical field, namely, methods of forming pharmaceutical bottles. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Forte's teaching of using several blends or alloys which include dyes in the final molding composition which

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is molded by Firestone's general molding method after being mixed in a desired order in order to provide the blue tinting and UV protection factor for the molded article (see Forte, Para 0016-0017).

Response to Arguments

Applicant's arguments with respect to claim 13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A. Huson whose telephone number is 571-272-1198. The examiner can normally be reached on Monday-Friday 7:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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